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In re Application of
Nguyen et al :
Serial No : 09/555,640 :Petition To Review Restriction
Filed : 10 August 2000 :Under 37 C.F.R. 1.144
Attorney Docket No.: 045636-5033-US :

This is in response to applicants petition under 37 CFR 1.144, filed May 2, 2003, requesting review of the Examiner's restriction requirement mailed 02/01/2003. The delay in acting on this petition is regretted.

BACKGROUND

This application is a national stage filing of PCT/FR98/02615, filed 3 December 1998. The Examiner instituted a restriction of claims 1-14, 16-21, 24-37 into 8 different Groups in an office action mailed 12 June 2002 which was subsequently made final. The Groups are set forth below:

Group I, claims 1-6 and 10, drawn to nucleic acids, fragments and primer pairs.

Group II, claims 7-9, drawn to variant erythrovirus or plasmids encoding said variants.

Group III, claims 11-14, 16, 24-27 drawn to diagnostic methods employing various nucleotide sequences.

Group IV, claims 17-20, 28, 29 drawn to proteins or polypeptide fragments and immunogenic compositions containing such

Group V, claims 21, 30, 31 drawn to antibody directed against an erythrovirus variant protein or polypeptide fragment thereof.

Group VI, claims 32 and 33, drawn to in vitro screening methodologies employing erythrovirus peptides.

Group VII, claims 34 and 35 drawn to in vitro screening methodologies employing erythrovirus-specific antibodies

Group VIII claims 36 and 37 drawn to diagnostic kit comprising various reagents.

Applicants were then required to elect a single product for examination.
Applicants elected Group I and SEQ ID No. 1 with traverse.

On 25 February 2003, the Examiner considered the traversal and found it to be not persuasive. The restriction requirement was made final. Claims 3-14, 16-21 and 24-37 were withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 1 and 2 were rejected under 35 USC 112, second paragraph for referring to non-elected claims. The erythrovirus genome segment corresponding to SEQ ID No 1 was indicated as being free of the prior art of record.

RELEVANT AUTHORITY

An international or a national stage application are considered to have unity of invention where there exists a "special technical feature" that defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See PCT Rule 13.2; 37 CFR 1.475(a), (b)(1) and (2).

PCT 13.2 Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled

> *Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.*

See MPEP 1893.03(d) and Annex B, Part 2 of the PCT Administration Instructions

MPEP 1850 states *Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims and*

> *(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims;*
> *(ii) If however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on the claim need to be carefully considered. If there is no link remaining an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised.*

See ANNEX B: Unity of Invention Part 1 "Instructions Concerning Unity of Invention" MPEP AI-6 (Rev. 1. Feb. 2003).

Regarding the determination of a "special technical feature" under Rule 13.2 when dealing with "Markush Practice", MPEP: Annex B "Unity of Invention Part 1 Instructions Concerning Unity of Invention" and "Part 2 Examples Concerning Unity of Invention" is instructive.

In accordance with Annex B (f) "Markush Practice", the requirement of a technical interrelationship and the same or corresponding special technical feature as defined in Rule 13.2, shall be considered to be met when the alternatives are of a "similar nature" which occurs when the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B)(1) a common structure is present, i.e. a significant structural element is shared by all of the alternatives, or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a "recognized class of chemical compounds" in the art to which the invention pertains.

MPEP 809.03 defines linking claims as follows:
There are a number of situations which arise in which an application has claims to two or more properly divisible inventions, so that a requirement to restrict the application to one would be proper, but presented in the same case are one or more claims (generally called "linking" claims) inseparable therefrom and thus linking together the inventions otherwise divisible.

37 CFR 1.475(b)-(d) provides guidance for treatment of second and subsequent products and methods.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
(c) If an application contains claims to more or less than one of the combinations of

categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

37 CFR 1.475(e) states:
(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

DISCUSSION

The application, file history and petition have been considered carefully.

Relevant claims are summarized below.

Claim 1. An isolated nucleic acid comprising nucleic acids selected from the groups consisting of:

the sequence is SEQ ID No 1,

the genomic sequences of variant erythroviruses called erythrovirus type V9, which molecularly cannot be recognized as an erythrovirus B19 because it exhibits greater than or equals to 10% over the whole genome with respect to the erythrovirus B19 sequences and which exhibits a genetic divergence of less than or equal to 6% with respect to SEQ ID No 1, and

the erythrovirus genomic sequences capable of hybridizing under stringent conditions with one of the following sequences: sequences SEQ ID Nos. 45-80, 81, 83, 85, 87, 89, 91, 93, 108, 110, 117, 118, 119 and 120.

Claim 2. The nucleic acid of Claim 1 wherein the nucleic acid exhibits a restriction profile according to Figures 7.1 to 7.3.

Claim 3. Fragments of the nucleic acids according to Claim 1, which are capable of allowing detection of an erythrovirus V9, characterized in that they are selected from the Group consisting of:
a) the sequences SEQ ID Nos 81, 83, 85, 87, 89, 91 or 93
b) the sequences SEQ ID Nos 2-80
c) the sequences SEQ ID Nos 105-121 and

d) the sequences complementary to the preceding sequences, wherein the fragments comprise at least 17 nucleotides derived from the preceding sequences or their complementary sequences.

Claim 4. A fragment according to Claim 3, selected from the groups consisting of SEQ ID Nos :45-80, 108 and 110, their complementary sequences, the sequences of at least 17 nucleotides derived from these sequences and the sequences comprising the said sequences and wherein the selected sequence is capable of serving as a probe in the specific identification of an erythrovirus V9 or related erythrovirus.

Claim 5. A fragment according to Claim 3, selected from the group consisting of the sequences SEQ ID Nos 2-80 and the sequences SEQ ID No 105-121, their complementary sequences, the sequences of at least 17 nucleotides derived from these sequences and the sequences comprising the said sequences and wherein the selected sequence is capable of serving as a primer for the amplification of sequences derived from an erythrovirus.

Claims 7 and 8 are directed to a virus or plasmid that comprises the viral genome of a variant erythrovirus called V9, described generally in terms of Claim 1, second clause.

Claim 9 is reproduced below:

9. A plasmid, according to Claim 8, characterized in that it includes the sequence of SEQ ID No. 1.

It is noted that the elected invention, nucleic acid comprising SEQ ID No. 1, and nucleic acid as recited in Claim 9 are one and the same. As such, the examiner erred in withdrawing Claim 9 from examination. Moreover, because Claim 9 is properly dependent upon claim 8 and because claim 8 is of comparable, overlapping scope with claim 7, these claims should also have been examined along with the elected invention, molecules comprising SEQ ID No. 1 or variants of SEQ ID No. 1. Finally, because sequences comprising SEQ ID No. 1 are free of the prior art, as stated in the Office action, Claim 9 should have been rejoined as it would also share the special technical feature and make a contribution over the prior art. In view of this error, both the lack of unity determination and the Office action have been vacated.

Before turning to the merits of the petition, a number of problems listed below in the claims complicate interpretation what applicants intend to claim.

(1) Claim 1 recites nucleic acid comprising nucleic acids and lists a Markush group. It is not clear whether applicant intended to make the second phrase "nucleic acids" plural, thus requiring two of the molecules, for example SEQ ID No 1 and SEQ ID No 45, together. Alternatively, if the second phrase "nucleic acids" contains a

typographical error, the scope of Claim 1 only requires one of the particular sequences recited.

(2) Similarly, Claim 3 recites "Fragments of nucleic acids according to Claim 1..." Again, it is not clear whether applicants intend to claim sets of molecules or whether the term fragments contains a typographical error and should be in the singular, not plural form. A review of dependent Claims 4 and 5 does not resolve this uncertainty.

(3) Claims 4 and 5 recite "Fragment according to claim 3..." One fragment is broader that sets of fragments. It is not clear whether Claims 4 and 5 are improper dependent claims which do not further limit the scope of the claims 1 and 3 or whether Claims 4 and 5 contain a typographical error and should recite "fragment" in the plural, not singular form.

(4) Claim 4 is directed to sequences comprising said sequences of claim 3. In this respect, claim 4 appears to be an improperly dependent claim in that it is broader in scope then fragments of claims 3 or 1. Similarly claims 4 and 5 recite sequences "derived from" those in claims 1 and 3. These sequences also appear to be broader in scope then the ones in the preceding claims. Applicants are reminded that dependent claims must be narrower than the claim(s) from which they depend.

(5) Claims 4 and 5 also recite sequences derived from said sequence and sequences comprising the said sequences. This appears to read upon sequences which share only a small amount of sequence homology with any of the recited fragments and may contain a large amount of unrelated sequence.

(6) The functional limitations recited in Claims 4 and 5 do not further limit the scope of the claim to sequences specific for V9, because they encompass probes for any related erythorovirus or primers for sequences derived from any erythrovirus.

(7) Claim 18 recites a protein which is not characterized by structure or function. The protein is characterized in the manner in which it is made. It is not clear whether any of the nucleotide sequences of Claim 1 are meant to function as the template from which the protein is expressed or whether they function to enhance transcription or translation of other, unrecited sequences. For this reason it is difficult to place Claim 18 in any Group.

In view of items (1) through (7) above, it is not clear whether the claims read upon sequences in the alternative or in combination. Neither the lack of unity determination nor Office action addressed these problems or presented applicants with the opportunity to elect an invention directed to sets or combinations of sequences if that were the invention intended. Similarly, the lack of unity determination did not identify or address the possible combinations and sets of fragments which may be encompassed by the claims.

For example, the compositions of Claims 20, 28 and 29 are directed to one or more of the proteins. These claims encompass both individual molecules and sets of molecules.

Additionally, the kits of claim 36 encompass at least one probe and/or a pair of primers and/or a protein and/or an antibody. As such, this claim reads upon and should be examined with any elected product group.

Claim 6 clearly sets forth pairs of primers. As such, this claim would be included in the examination to the extent it reads upon a primer pair which required the elected invention.

In view of these problems with the claims, Applicants should carefully review the claims to ensure that they are claiming what they intend to claim.

Turning now to the petition, it states that all of the sequences set forth in Claim 1 are properly examined as a whole because SEQ ID No. 1 is nearly full length genomic clone of erythovirus V9 and has been indicated as free of the prior art by the examiner.

This is not persuasive, because the molecules encompassed by claim 1 are not commensurate in scope with the features argued. The molecules encompassed by the third clause of claim 1 are short primer sequences which are clearly not full length genomic clones of erythovirus V9. A review of the sequence listing shows that SEQ ID No. 1 is 5028 nucleotides in length. In contrast, SEQ ID No. 45 is 120 nucleotides in length. Moreover, SEQ ID No. 46 is 30 nucleotides in length. The structure shared by these sequences, 30 residues of SEQ ID NO 46, is not a significant structural element of SEQ ID No. 1, which is 5028 in length.

Applicants have argued that the sequence search of the various fragments of SEQ ID No. 1 would overlap. This argument is not persuasive. An overlapping search is not the same as a co-extensive search. Moreover, search burden is not a criteria for determining unity of invention.

Applicants then argue that Groups are linked by the special technical feature of Group I because they all share the common technical feature of sequence of Group I. This is not persuasive because (1) the fragments of SEQ ID No 1 do not require the entire length of SEQ ID No. 1, (2) the fragments do not require any particular structural portion of SEQ ID No. 1 and (3) the fragments do not require any particular function, property or activity which is shared with SEQ ID No. 1.

Applicants argue that SEQ ID No. 1 links all the sequences claimed. This is not correct. While the fragments may have been derived from or complementary to or hybridize to SEQ ID No. 1, the fragments are not linked, per se, by SEQ ID No. 1. Moreover, it is noted that while broad claim may link narrower claims, narrow claims cannot link broad claims. SEQ ID No. 1 cannot link fragments of SEQ ID No. 1. The broadest claimed embodiment appears to be one of:

"sequences capable of hybridizing under stringent conditions with" (claim 1, third clause)
"sequences complementary to the preceding sequences, wherein the fragments comprise at least 17 nucleotides derived from the preceding sequences" of claim 3 or
"sequences of at least 17 nucleotides derived from these sequences and the sequences comprising said sequences" of claim 4.

This appears to be the concept which links the other polynucleotide product inventions. Although applicants have mis-identified the linking concept, they are correct that one exists which was not properly addressed by the Examiner

All of the polynucleotide sequences appear to be linked by one or more of the following concepts:

"sequences capable of hybridizing under stringent conditions with" (claim 1, third clause)
"sequences complementary to the preceding sequences, wherein the fragments comprise at least 17 nucleotides derived from the preceding sequences (Claim 3)
"sequences of at least 17 nucleotides derived from other sequences" and
"sequences comprising said sequences." (Claim 4).

Therefore, Claims 1, 3 and 4, in part, appear to link(s) inventions directed to the various polynucleotide sequences. The restriction requirement among the linked inventions would be subject to the nonallowance of the linking claim(s), claims which contain these limitations. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Additionally, overlapping subject matter is found between the various polynucleotides, as follows. Claim 4 recites "sequences comprising said sequences." The term "comprising" is considered to be open claim language and allows for the addition of other sequences to the end of the particular sequence.

In this case, a restriction to a single sequence, for example a fragment, may result in a group which overlaps in scope with a group drawn to a larger molecule which

comprises that fragment. If a large molecule is elected and found free of the prior art, it does not then follow that the fragments of that molecule are free of the prior art.

However, if applicants elect a fragment of a full-length molecule and that fragment was not found in the prior art, either alone or as a part of a larger prior art molecule, then any disclosed molecule which contains at least the entire examined fragment would be rejoined as no further search would be required. If however, the smaller fragment were found in the prior art, either alone or as part of a larger molecule, then no rejoinder would be contemplated because the shared common feature would not be considered a special technical feature under PCT Rule 13.2.

By way of example, it appears that SEQ ID No 85 is contained within and therefore linked to SEQ ID No 1. If SEQ ID No 85 were elected and found to be free of the prior art, then the restriction requirement between SEQ ID No 85 and SEQ ID No 1 would be withdrawn.

In another example, SEQ ID No 26 (55-mer) appears to be contained within and linked to SEQ ID NO 83 (222-mer) which appears to be contained within and linked to SEQ ID No 81 (2013-mer) which appears to be contained within and linked to SEQ ID No 1. If SEQ ID No 26 is elected and found to be free of the prior art, then the restriction requirement between SEQ ID Nos. 26, 83, 81 and 1 would be withdrawn.

The lack of unity determination failed to inform applicants of the possibility for rejoinder of larger molecules that contain the elected sequence, should that sequence make a contribution over the prior art. Should another lack of unity determination be prepared, Applicants should be informed of the possibility of this type of rejoinder and of the reasons for carefully considering the size of the sequence applicants wish to elect. Applicants should note that the rejoinder will apply only to sequences that are not previously allowed or patented. Thus, if Claims directed at SEQ ID No 85 was found free of the prior art and rejoined and issued with SEQ ID No 1, claims encompassing SEQ ID No 1, for example, sequences comprising SEQ ID No 83, would not be allowed without a terminal disclaimer. The Office will not issue claims to the same sequence in more than one patent.

This application contains claims to a product and a method of using the product. Should the product be elected and found to make a contribution over the prior art, and should the method claims be limited in scope to that product, the first method of using the product would be rejoined, in view of the shared special technical feature.

If multiple methods of using the elected product are claimed, applicants should be informed of rejoinder practice for the second and subsequent methods of using the product. See MPEP 821.04.

DECISION

Applicant's petition to withdraw the restriction requirement under 37 CFR 1.144 is **GRANTED** to the extent that the lack of unity determination mailed 12 June 2002 and the office action mailed 25 February 2003 have been vacated.

The application will be forwarded to the Examiner for consideration of the response and amendment filed 25 August 2003 and for preparation a new Office action consistent with this petition decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, Special Program Examiner, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600.

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